1. Submitter

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DEC 0 2 2013

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Date Summary Prepared: May 17, 2013

2. Device Name

Trade	NiTiFLEX Stapes Prosthesis
	Detroit Piston
	Skarzynski Piston
	Roberson Stapes Prosthesis
Common	Stapes Prosthesis, Stapes Piston
Classification	Prosthesis, Partial Ossicular Replacement
Product Code	77 ETB
Regulation #	CFR 874.3450

3. Predicate Devices

K002221	K-Piston, Heinz Kurz GmbH Medizintechnik
K021479	CliP® Piston áWengen, Heinz Kurz GmbH Medizintechnik
K112616	NiTiBOND Stapes Prosthesis, Heinz Kurz GmbH Medizintechnik
unknown	Big Easy, Medtronic
K002897	Roberson Stapes Prosthesis, Medtronic

4. Device Description

Due to different preferences and different techniques of the surgeons various designs of stapes prosthesis are available. The objective of all stapedial prostheses is the restoration of the mechanical transfer of sound from the tympanic membrane to the oval window of the cochlear with the least impairment of hearing.

NiTiFLEX Stapes Prosthesis:

The NiTiFLEX is a stapes prosthesis for partial replacement of the ossicular chain.
It consists of a Nitinol clip and the standard KURZ shaft (piston) made of pure titanium with a diameter of 0.4 and 0.6 mm (ASTM F67).
The Nitinol clip is made of superelastic Nitinol. Due to the CliP Design, already available with the predicate device CliP® Piston àWengen, the NiTiFLEX can be fixed on the long process of the incus without manual crimping. With the superelastic characteristics of the loop the easier handling of the application of the CliP can be achieved.

Detroit Piston:

The Detroit Piston is a stapes prosthesis for partial replacement of the ossicular chain.
It is made of pure titanium (ASTM F67). As shaft the standard KURZ piston is used with a diameter of 0.4 / 0.5 / 0.6 mm.
The loop has got a width of 0.5 mm and is twisted (like the loop of the predicate device K-Piston) for easier application on the long process of the incus especially in cases were the incus diameter is very small. The attachment to the incus is done by manual crimping of the prosthesis loop.

Roberson Stapes Prosthesis

The Roberson Stapes Prosthesis is a stapes prosthesis for partial replacement of the ossicular chain.
It is made of pure titanium (ASTM F67). The long process of the incus is placed within the bucket. Two different diameters of the bucket are available - 0.9 and 1.0 mm – for different incus diameters. A piston diameter of 0.6 mm is used. Additional stability is provided by the wire that is placed over the incus.
This design is comparable to the Roberson Stapes Prosthesis by Metronic (predicate device).

Skarzynski Piston

The Skarzynski Piston is a stapes prosthesis for partial replacement of the ossicular chain.
It is made of pure titanium (ASTM F67). As shaft the standard KURZ piston is used with a diameter of 0.4 and 0.6 mm. The loop has got a width of 0.25 mm and is twisted (like the loop of the predicate device K-Piston) for easier application on the long process of the incus especially in cases were the incus diameter is very small. The attachment to the incus is done by manual crimping of the prosthesis loop.

5. Statement of Intended Use

KURZ middle ear prostheses are intended for the partial or total surgical replacement of the ossicular chain of the human middle ear. The objective is the restoration of the mechanical transfer of sound from the tympanic membrane to the oval window of the cochlear with the least impairment of hearing.

Specifically, the devices are designed for the treatment of

1. Chronic middle ear inflammation (also following removal of a tumour, e.g. cholesteatoma) with functional impairment of the ossicular chain
2. Otosclerosis (stapedial fixation) / congenital stapedial fixation
3. Traumatic injury to the ossicular chain
4. Malformation of the middle ear
5. Revision surgery to correct inadequate hearing improvement, e.g. through dislocation of a prosthesis

The indications are identical to the predicate devices and therefore do not affect safety and effectiveness.

6. Comparison with Predicate Devices

Due to different preferences and different techniques of the surgeons various designs of stapes prosthesis are available. The objective of all stapedial prostheses, including the predicate devices, is the restoration of the mechanical transfer of sound from the tympanic membrane to the oval window of the cochlear with the least impairment of hearing.

Device	NiTiFLEX Stapes Prosthesis Heinz Kurz GmbH	PREDICATE DEVICE CliP® Piston áWengen Heinz Kurz GmbH K021479	PREDICATE DEVICE NiTiBOND Heinz Kurz GmbH K112616
Design Comparison			
Intended Use	The prosthesis is intended for ossicular replacement to restore functionality to the middle ear in cases of pathological changes of the sound transmission system.	Identical	Identical
Method of Attachment	Manually, without crimping	Manually, without crimping	Heat activated
# of Sizes	16 (8 for each shaft Ø)	16 (8 for each shaft Ø)	16 (8 for each shaft Ø)
Dimensions Length [mm]	3.5 – 5.5 (up to 5.0 in 0.25 mm intervals + 5.5 mm)	3.5 – 5.5 (up to 5.0 in 0.25 mm intervals + 5.5 mm)	3.5 – 5.5 (up to 5.0 in 0.25 mm intervals + 5.5 mm)
Piston Ø [mm]	0.4 / 0.6	0.4 / 0.6	0.4 / 0.6
Width of Loop Band [mm]	0.25	0.25	0.25
Materials **Loop** **Piston**	 Nitinol Titanium (ASTM F67)	 Titanium (ASTM F67)	 Nitinol Titanium (ASTM F67)
Single Use	Yes	Yes	Yes
Sterile	Yes	Yes	Yes
MRI	MR Conditional 1.5, 3 + 7 Tesla	MR Conditional 1.5, 3 + 7 Tesla	MR Conditional 1.5, 3 + 7 Tesla
Biocompatible	Yes	Yes	Yes

Device	Detroit Piston Heinz Kurz GmbH	Skarzynski Piston Heinz Kurz GmbH	PREDICATE DEVICE K-Piston Heinz Kurz GmbH K002221	PREDICATE DEVICE Big Easy Medtronic 510(k) number unknown
Design Comparison				
Intended Use	The prosthesis is intended for partial ossicular replacement to restore functionality to the middle ear in cases of pathological changes of the sound transmission system.	Identical	Identical	Identical
Method of Attachment	Manually, with crimping	Manually, with crimping	Manually, with crimping	Manually, with crimping
# of Sizes	24 (8 for each shaft Ø)	16 (8 for each shaft Ø)	28 (14 for each shaft Ø)	10 (4 straight, 3 each left ear offset / right ear offset)
Dimensions Length [mm]	3.5 – 5.5 (up to 5.0 mm in 0.25 mm intervals + 5.5 mm)	3.5 – 5.5 (up to 5.0 mm in 0.25 mm intervals + 5.5 mm)	3.5 – 10.0 (up to 5.50 in 0.25 mm intervals; than 1.0 mm intervals)	4.00 – 5.00 (0.25 mm intervals)
Piston Ø [mm]	0.4 / 0.5 / 0.6	0.4 / 0.6	0.4 / 0.6	0.5
Width of Loop Band [mm]	0.5	0.25	0.3	0.4
Materials Loop Piston	Titanium (ASTM F67)	Titanium (ASTM F67)	Titanium (ASTM F67)	Platinum Titanium
Single Use	Yes	Yes	Yes	Yes
Sterile	Yes	Yes	Yes	Yes
MRI	MR Conditional 1.5, 3 + 7 Tesla	MR Conditional 1.5, 3 + 7 Tesla	MR Conditional 1.5, 3 + 7 Tesla	MR Conditional
Biocompatible	Yes	Yes	Yes	Yes

Device	Roberson Stapes Prosthesis Heinz Kurz GmbH	PREDICATE DEVICE Roberson Stapes Prosthesis Medtronic 510(k) number unknown
Design Comparison		
Intended Use	The prosthesis is intended for ossicular replacement to restore functionality to the middle ear in cases of pathological changes of the sound transmission system.	Identical
Method of Attachment	Manually, without crimping	Manually, without crimping
# of Sizes	6 (3 for each bucket Ø)	6 (3 for each bucket Ø)
Dimensions Length [mm]	4.0 – 4.5 (0.25 mm intervals)	4.0 – 4.5 (0.25 mm intervals)
Piston Ø [mm]	0.6	0.6
Bucket Ø [mm]	0.9 / 1.0	0.9 / 1.0
Materials	Titanium (ASTM F67)	Titanium (ASTM F67)
Single Use	Yes	Yes
Sterile	Yes	Yes
MRI	MR Conditional 1.5, 3 + 7 Tesla	MR Conditional
Biocompatible	Yes	Yes

7. Performance Testing

Safety and effectiveness has been demonstration within the Bench testing and performance specifications are met.

The following tests were conducted:

- NiTiFLEX: Attachment Forces

All products:

- MRI environment according ASTM F2119, F2052, F2182
- Biocompatibility according EN ISO 10993
- Shelf life testing according EN ISO 11607
- Sterilization validation according EN ISO 11137-1, 11137-2; Gamma Sterilization with a confirmed sterility assurance level of $< 10^{-6}$
- Packaging validation according EN ISO 11607

8. Conclusion

Nonclinical and clinical testing demonstrated that the Kurz Stapes Prostheses are as safe and effective as the predicate devices. The results of non-clinical design performance validations raise no new issues of safety and effectiveness.

Differences between the Kurz Stapes Prostheses and the predicate devices should not affect the safety or effectiveness.

Date: 17-May-2013

Signature:

Kristina Bitzer
Manager Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

December 2, 2013

Heinz Kurz GmbH Medizintechnik
c/o Ms. Kristina Bitzer
Manager Regulatory Affairs
Tübinger Strasse 3
72144 Dusslingen
Germany

Re: K130512
Trade/Device Name: NitiFLEX Stapes Prosthesis, Detroit Piston, Skarzynski Piston, Roberson Stapes Prosthesis
Regulation Number: 21 CFR 874.3450
Regulation Name: Partial Ossicular Replacement Prosthesis
Regulatory Class: Class II
Product Code: ETB
Dated: October 28, 2013
Received: October 31, 2013

Dear Ms. Bitzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130512

Device Name: NiTiFLEX Stapes Prosthesis
Detroit Piston
Skarzynski Piston
Roberson Stapes Prosthesis

Indications For Use:

KURZ middle ear prostheses are intended for the partial or total surgical replacement of the ossicular chain of the human middle ear. The objective is the restoration of the mechanical transfer of sound from the tympanic membrane to the oval window of the cochlear with the least impairment of hearing.

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2. Otosclerosis (stapedial fixation) / congenital stapedial fixation
3. Traumatic injury to the ossicular chain
4. Malformation of the middle ear
5. Revision surgery to correct inadequate hearing improvement, e.g. through dislocation of a prosthesis

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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